

**FCC & FDA *Public Meeting on Enabling the Convergence of
Communications and Medical Systems***
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Current State of Wireless in Healthcare & Lessons Learned

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Elliot Sloane's Bio Brief

- 35+ years in the medical technology and IT/HIT fields, as a technology/engineering expert and consumer/safety advocate
 - Biomedical and Clinical Engineering core
 - Information Systems and Sciences doctorate
- 25 years as a CIO, COO, CTO, CRO in the medical technology industry (ECRI Institute & MEDIQ, Inc)
- 10+ years in business schools, MIS, CS
- Currently ***Health Systems Engineering Program Director and Research Professor*** at Drexel University

Full Disclosure

- I have no direct or indirect economic interest in, nor derive economic benefit or support from, any medical device or electronic health record software company
- I hold or have held uncompensated board/member/chair roles with multiple non-profits, including ACCE, AHTF, CHIRP, IEEE EMBS, and RFID in Health Consortium, and with Standards Development Organizations including ANSI, IEEE-SA, IHE International, and IHE USA
- I do provide consulting services to US gov't, the World Health Organization, and other government, educational, and non-profit agencies
- Specializations: electronic health records, medical devices, privacy, security, and patient safety, wireless in healthcare, and related technical standards and policies

Sources for this presentation?

- My own research, papers, and presentations for AAMI, AMCIS, Computer Society, HIMSS, IEEE and similar peer-refereed sites beginning in 2002, and
- A series of six (6) 70-150 person cross-industry “Wireless in Healthcare” meetings held between December, 2008 and June 2009 in DC, IL, NJ, NY, MD, and PA
 - Included medical device, EHR, telecom, and RFID manufacturers, telecom vendors, standards and trade associations, clinicians, hospitals, and participants from VA, FDA, & FCC
- 3-day *FDA Medical Device Interoperability Workshop* held at the FDA in Silver Spring in Jan ‘10
- IEEE and ANSI-HITSP Standards Workgroups
- Many other research articles and conference presentations

Lessons Learned

1. Wireless in Healthcare is pervasive and ubiquitous.
2. Convergence of Information and Computer Technologies (ICT) multiplies the rate of Convergence of Medical Devices with ICT.
3. Federal investments in Electronic Health Records are accelerating adoption of wireless medical systems.
4. Adoption and deployment of wireless medical systems outpace standards, regulations, and accreditation programs

What we learned from our Wireless in Healthcare Workshops?

Wireless has become ubiquitous and pervasive!

- **Hospitals**
- **Physician Practices**
- **Free-standing clinics, surgi-centers, ER's, etc**
- **Skilled nursing facilities**
- **Rehabilitation hospitals**
- **Long term care facilities**
- **Assisted living facilities**
- **Home Care services**

– AND...

Where ELSE is “Wireless in Healthcare?”

- Emergency and First Responder Services
- Critical pharmaceutical and med/surg supply mgmt
- Inter- and Intra-enterprise clinical and security communications
- Social networking and internet-based research regarding healthcare
- Patient/family entertainment and hospitality services
- Electronic Patient Records (aka, EMR, EHR, PHR)
 - e.g., “Meaningful Use” requires physicians, other clinical providers, and physician practices and hospitals to use Computerized Provider Order Entry and ePrescribing regardless of location for Medicare and Medicaid...
- Self-managed personal medical care, fitness, and wellness activities in the home, at work, and “on the go”
 - *And more is coming!*

More wireless is arriving daily:

- Machine to Machine (M2M) communication
 - Includes wireless Device-to-Device, Device-to-System, and System to System communications
 - M2M began as proprietary, single-vendor solutions; now rapidly staged for open source, multi-vendor solutions
- Robotic food, pharmacy, and supply delivery
- RFID for patient, product, or device location, tracking, data capture, or data transformation
- New iPhone, iPad, and Droid medical applications for physicians, nurses, and patients are constantly being released

A Wireless Medical Systems Map

Medical Device Semantics and Communication Modalities Use Cases

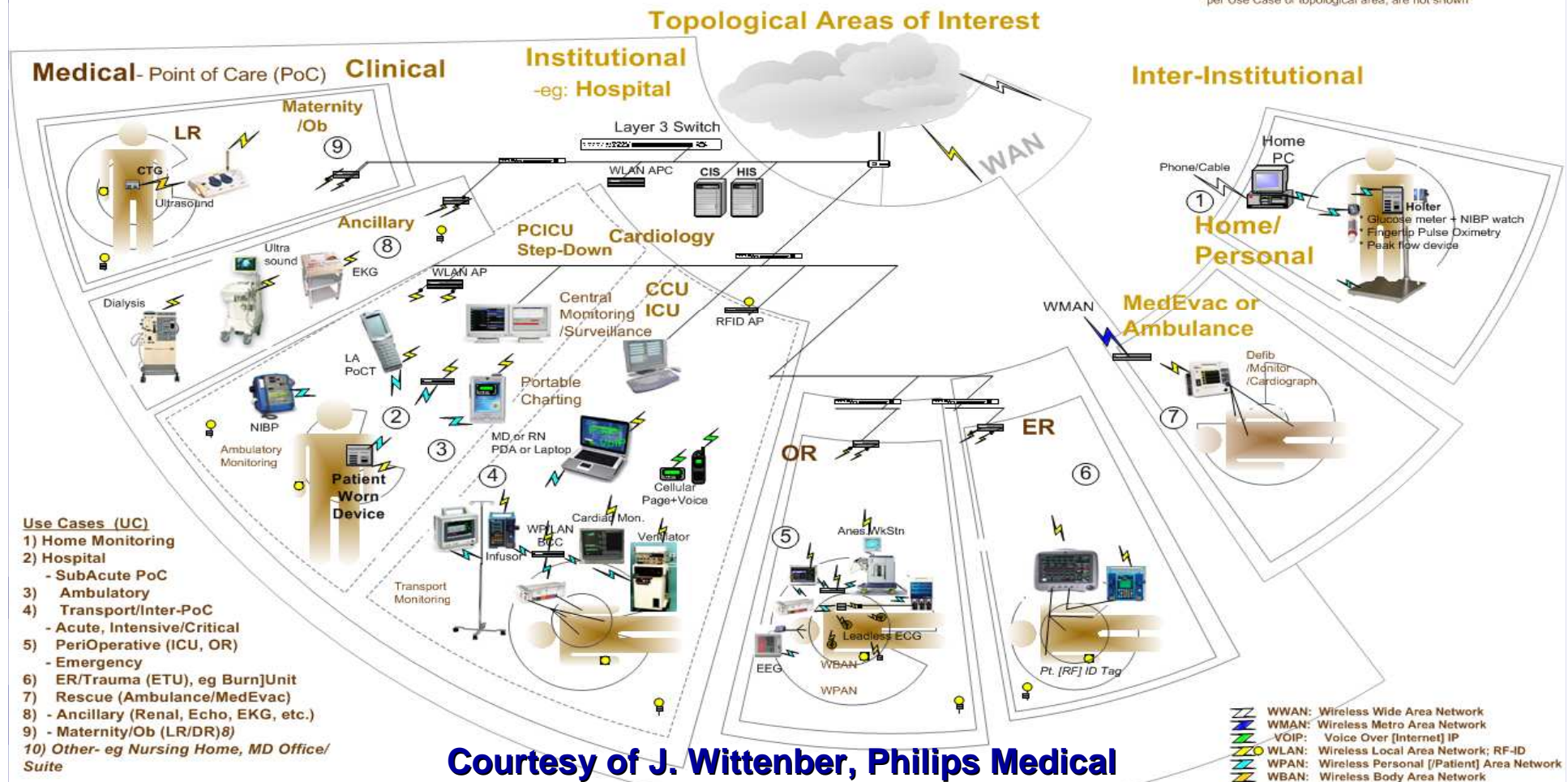
IEEE 11073.x and IEEE 802.x Standards At Work

22July10 Rev 4a

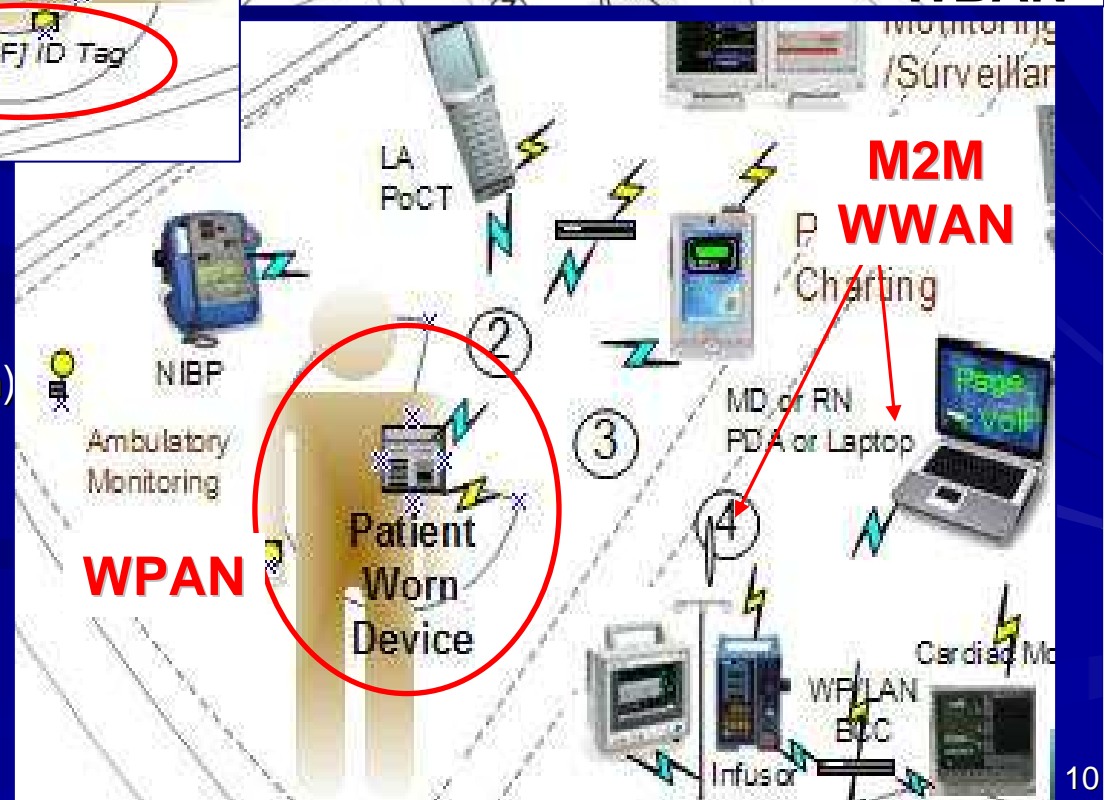
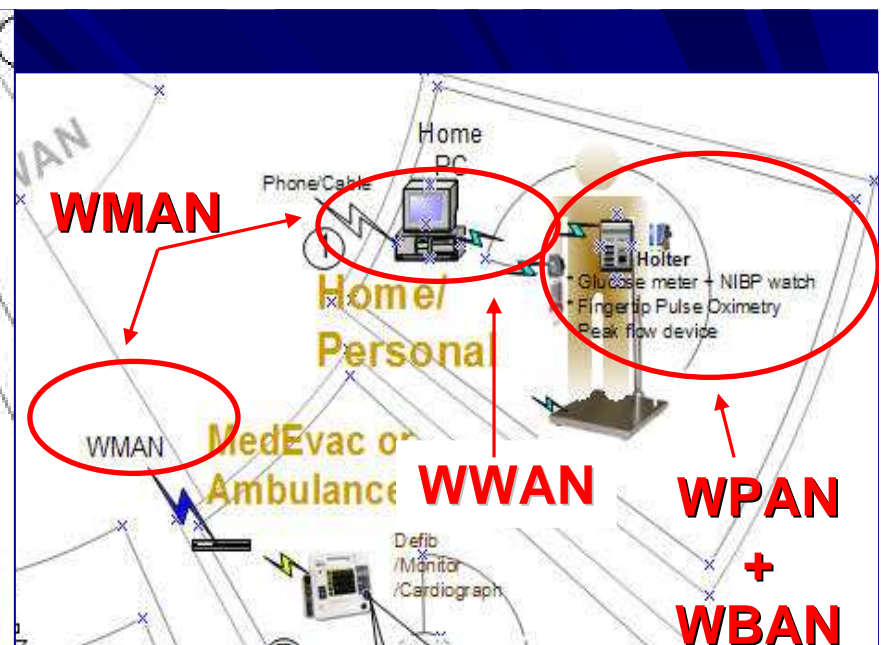
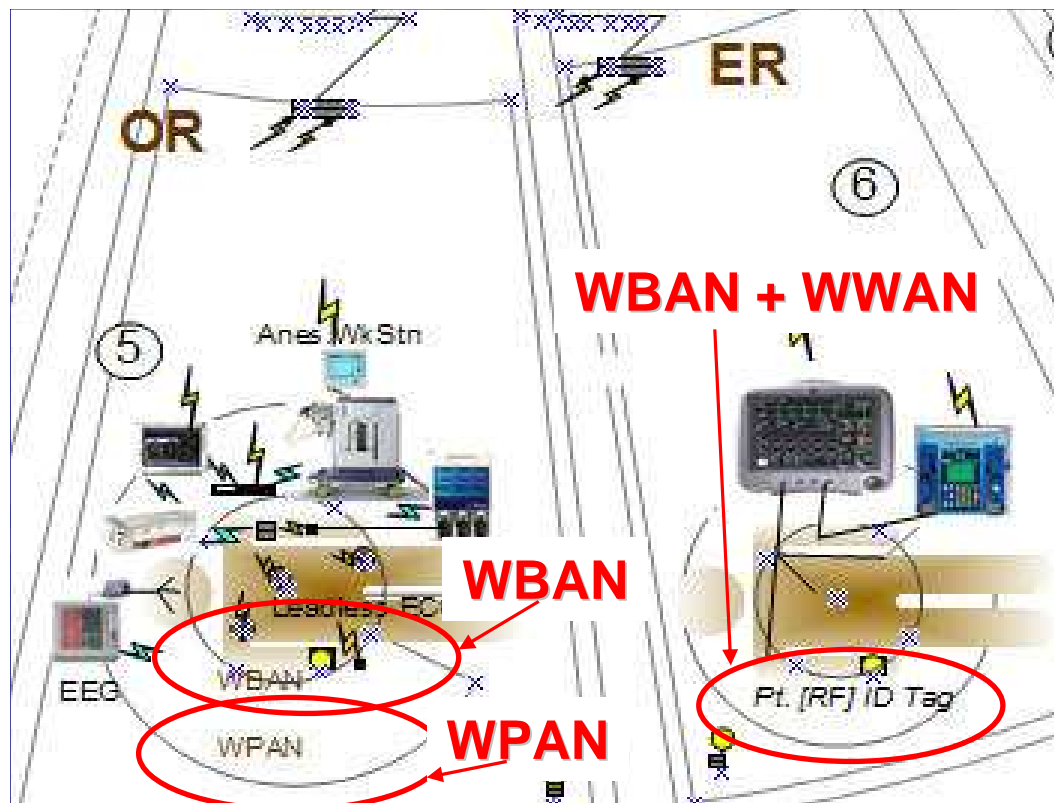
Note:

1) Drawings are intended to be representative of devices; do not take literally!!

2) Scaling factors, eg number of AP's or PWD's, etc., per Use Case or topological area, are not shown.



Courtesy of J. Wittenber, Philips Medical



Wireless medical system networks

- Body Area Network (ZigBee)
- Personal Area Network (Bluetooth)
- Wide Area Network (Wi-Fi)
- Metropolitan Area Network
 - Cellular
 - Wi-Max (4G)
 - 3G

These IEEE standards are posted for free access 6-months after publication at <http://standards.ieee.org/getieee802/>

- IEEE 802: [Overview & Architecture](#)
- IEEE 802.1™: [Bridging & Management](#)
- IEEE 802.2™: [Logical Link Control](#)
- IEEE 802.3™: [CSMA/CD \(Ethernet\) Access Method](#)
- IEEE 802.11™: [Wireless](#) (WAN - “Wi-Fi”, PAN – “Bluetooth”)
- IEEE 802.15™: [Wireless Personal Area Networks](#) (BAN/PAN, “ZigBee”)
- IEEE 802.16™: [Broadband Wireless Metropolitan Area Networks](#) (MAN – “Wi-Max”)
- IEEE 802.17™: [Resilient Packet Rings](#)
- IEEE 802.20™: [Overview and Architecture](#)
- IEEE 802.21™: [Media Independent Handover Services](#)

There are also Wireless Medical Telemetry frequencies

- http://wireless.fcc.gov/services/index.htm?job=service_home&id=wireless_medical_telemetry
- Those are separate from the above IEEE frequencies and applications just listed...

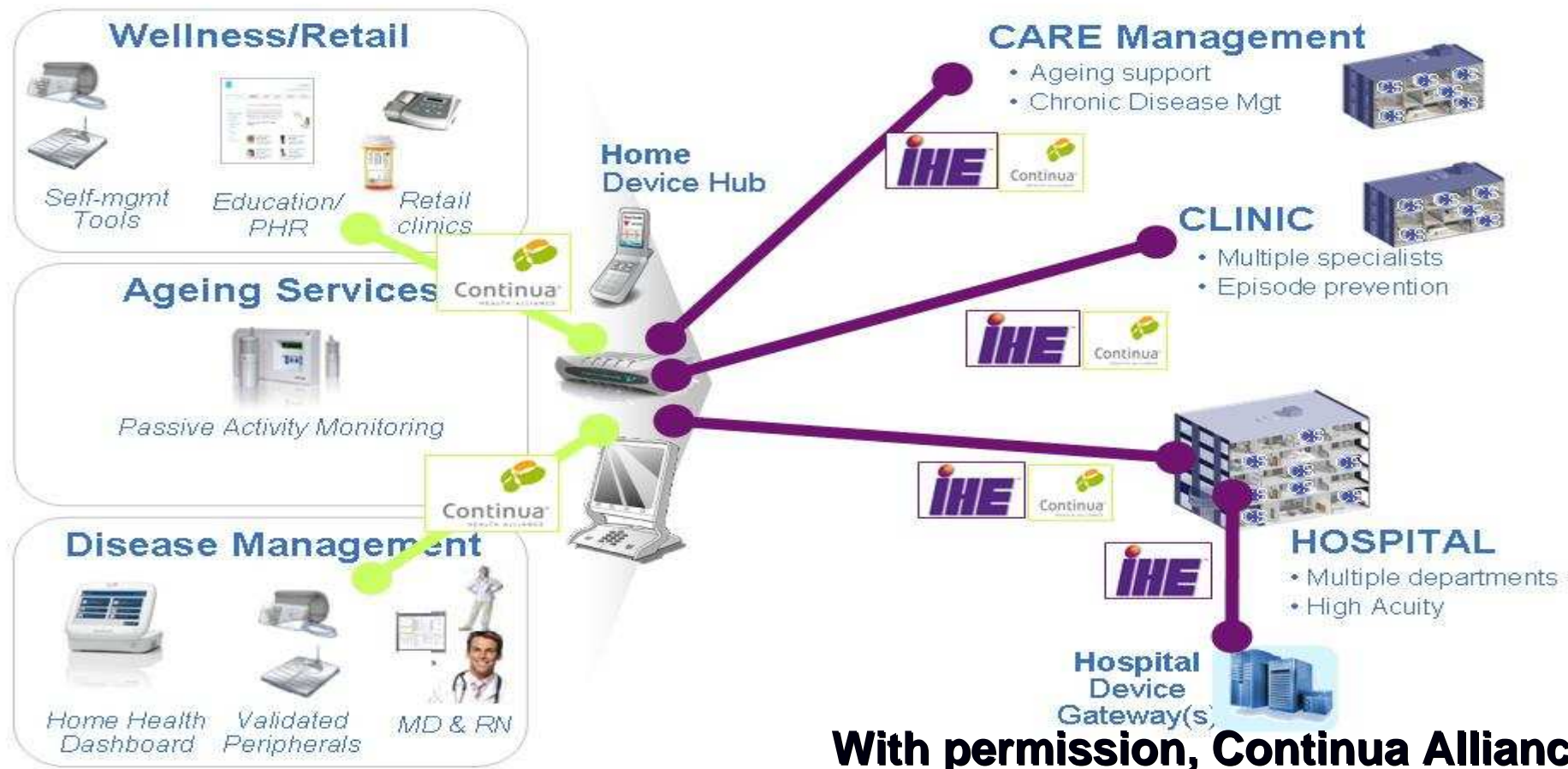
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Beginning this Fall, a single data interface architecture can be used by all Continua Personal Health Devices, all IHE-PCD Medical Devices, and all IHE EHRs!

Home health – Key connection Standardized

IHE and CONTINUA have agreed to support the a single common IHE DEC profile for feeding home device data and clinical device data into health records



This Continua-IHE interoperability standard alignment is an example of medical system and ICT convergence that was precipitated by the federal ANSI – HITSP EHR project.

- Will allow almost any brand of personal health device and/or any brand of clinical device to be used in any appropriate setting
- Can finally assure automatic and accurate data capture and eliminate error-prone manual entry
- Can provide near real-time update of Electronic Health Record/Personal Health Record as long as the wireless networks work properly

Acute care medical devices started moving to home care over 12 yrs ago!

A cell phone may be the ONLY link to caregivers.



From 8/14/2009 PBS NOW episode – “Gambling with Healthcare”
Rafael Comes Home segment, 8.2 minutes from episode start

“Acute” is taking on new, more intense meaning in hospitals...

Fla. preemie gets OK to leave hospital

Updated 2/21/2007 7:34 PM ET

E-mail | Save | Print | [RSS](#)



[Enlarge](#)

Baptist Health South via Getty Images

MIAMI (AP) — Parents of one of the world's smallest premature babies got to take her home Wednesday for the first time since she was delivered last fall.

Amillia Sonja Taylor has known only an incubator for a bed at Baptist Children's Hospital since she was delivered in October after less than 22 weeks in the womb.

"The baby is healthy and thriving and left Baptist Children's Hospital today after four months in our neonatal intensive care unit," hospital spokeswoman Liz Latta said.

Amillia, who was just 9 1/2 inches at birth and weighed less than 10 ounces, will still require oxygen at home and a developmental specialist will follow up with her and her parents to track her neurological development.

The infant now weighs about 4 1/2 pounds and is just over 15 1/2 inches

[Amillia Taylor Turns 2!](#)

Amillia's parents declined to



The world's most premature baby ever is celebrating a very special birthday.

Amillia Taylor, born at just 21 weeks and weighing only 10 ounces, turned 2 years old yesterday.

Her proud parents told [Local 10's Laurie Jennings](#) that Baby Amillia now weighs a healthy 26 pounds and is 26 1/2 inches tall.



Another ICT-Medical System Convergence “Multiplier” Example

- The CIMIT-ASTM-ICE (Integrated Control Environment) standard which will allow safe, real-time M2M control and connection, including Operating Room device interlocks and controls, closed-loop medical devices, and other innovations
- We are simply on the verge of being able to do medical care we only dreamed of...

Our 2008 and 2009 Wireless in Healthcare workshops revealed that

- “Convergence of Communications and Medical Systems” has broad impact!
 - e.g., “Medical Systems” wireless touches:
 - *Medical Devices/Systems, and*
 - *The hardware and software components of Health IT Systems, and*
 - *Many* other non-chemical or non-biological technologies inside and far away from hospitals that affect the safety and accuracy of patient diagnosis or therapy

The pieces that make up the whole may be less and less separable!

- Just as the modern ICT environment defies clear distinction, testing, or provisioning of computing, memory, and communications hardware and software,
- The Wireless Medical System enterprise is defying distinction and testing of any single component or subsystem for full testing, provisioning, protection, or validation
- CLEAR System of Systems Engineering (SoSE) environment and challenge!

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Re: Wireless in Medical System standards, regulations and accreditation programs

- This is because contemporary Wireless Medical Systems are very difficult to dissect and test piecewise, and
- The behavior of each component is interdependent on other components and subsystem in its environment – plus operator behaviors.
- e.g., A single defective gas pedal design appears to have caused a massive recall and product failure for Toyota.

Five Quick Conclusions

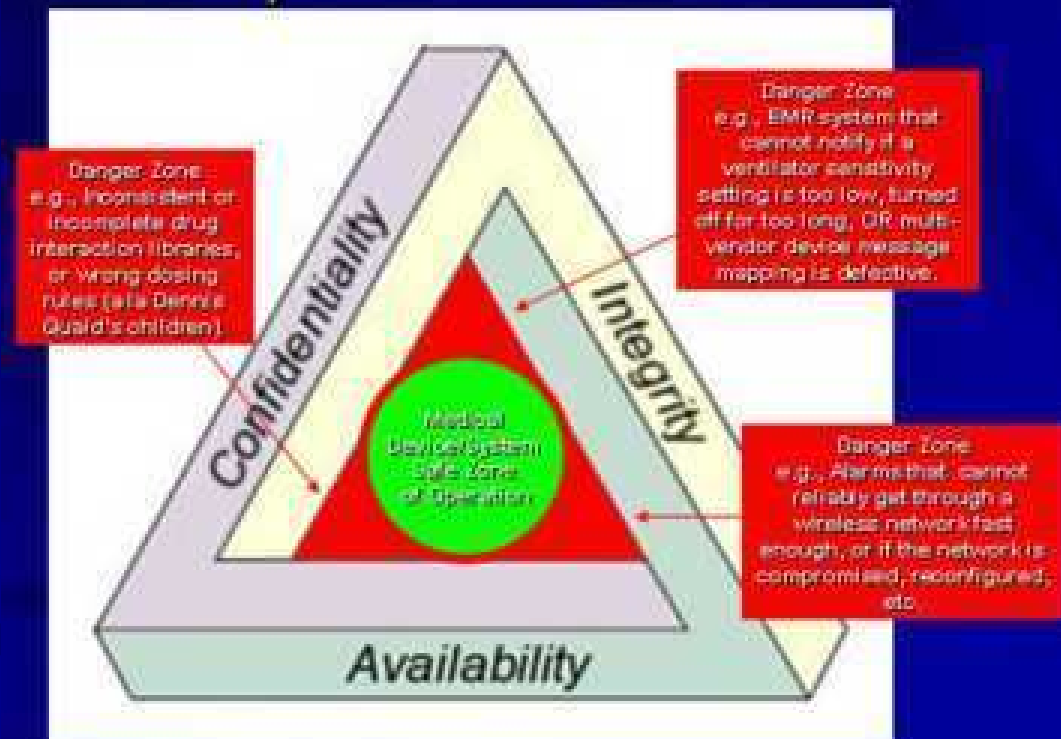
Our 2008 and 2009 Workshops suggested several activities, because the attendees cross-industry efforts to really understand and manage Wireless Medical Systems can help reduce our vulnerability to innovation delays and safety and performance risks.

It appeared to some attendees that failure to pay enough attention now may significantly slow the pace of medical advances, and our goals of safety, quality, and cost improvements

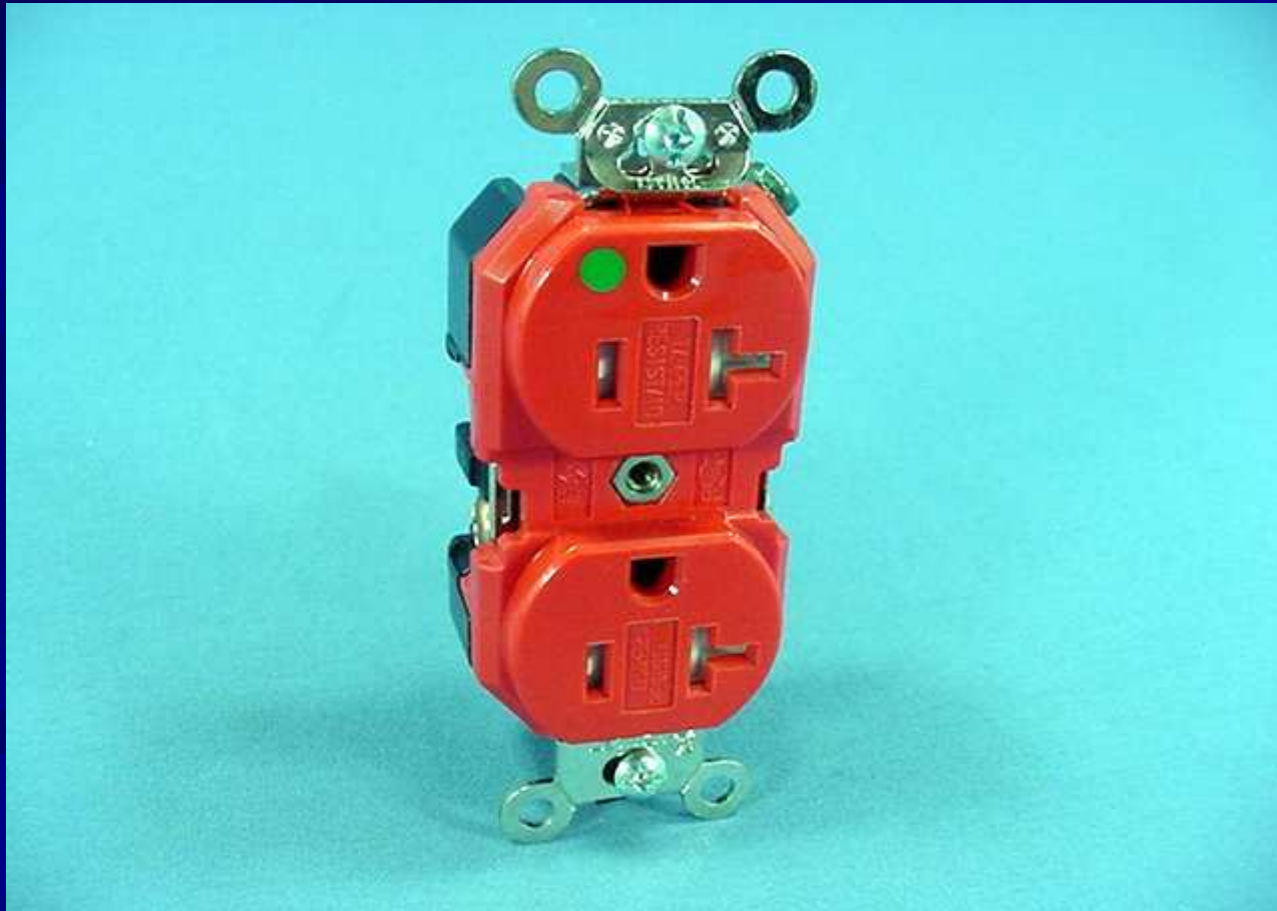
My suspicion and hope: CIA+S could become a framework for “HIPAA 2.0” and other discussions

- Confidentiality
- Integrity
- Availability
- Safety

This is also somewhat embodied in the emerging IEC 80001 medical network risk management framework.



Some of our Wireless Workshop attendees found value in discussing cross-industry “Medical Grade Wireless” standards, like current *Medical Grade Oxygen* and *Hospital Grade Electrical Outlets*.



Generalization of the above:

- Discussion, collaboration, standardization and coordination of orderly and safe “co-existence” among the many wireless healthcare modalities and applications would help immensely (and probably cannot be ignored for much longer.)
 - Frequency allocations
 - Quality of Service
 - Priority management
 - Bandwidth management
 - Security and access management

Facilities for Wireless Medical System and Interoperability Testing were requested by our Workshop Attendees

I intend to provision an initial system this winter at Drexel University's School of Biomedical Engineering, Science and Health Systems, and, quite frankly, several more are needed around the country to support R&D in this important area properly.

Thank you!

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ebsloane.org, [yahoo.com](http://www.yahoo.com), [hotmail.com](http://www.hotmail.com), etc.

or just Google™ me!!

Amillia Taylor Turns 2!

Your work DOES matter!

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Resources

- www.CEITCollaboration.org
- www.ContinuaAlliance.org
- www.HITSP.org
- www.IHE.net
- www.IHE.net/PCD
- <http://standards.ieee.org/getieee802/>